REMARKS

Claims 1-7, 10-36 and 40-73 are pending as shown in the paper filed June 5, 2006 and the examined claims were rejected under 35 U.S.C. § 112, 1st paragraph (written description).

Applicants reiterate the arguments presented in the paper filed June 5, 2006 and, in addition, draw the Examiner's attention to the recently published Federal Circuit case *Falkner et al. v. Inglis et al.* 05-1324 (Interference No. 105,187) (Federal Circuit, decided May 26, 2006), a copy of which is attached hereto for the Examiner's convenience.

In *Falkner,* the Federal Circuit reaffirmed that working examples are not required to satisfy the written description requirement, even for a broad genus (*see, Falkner,* page 14):

> Specifically, we hold, in accordance with our prior case law, that (1) examples are not necessary to support the adequacy of a written description (2) the written description standard may be (as it is here) even where actual reduction to practice of an invention is absent; and (3) there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.

With particular regard to recitation of known structures, the Federal Circuit reaffirmed that adequate written description does not require re-description of the sequence of known molecules and that literature available at the time of filing must be considered in determining the adequacy of the written description (*Falkner*, pages 17-18):

> Indeed, a requirement that patentees recite known DNA structures, if one existed, would serve no goal of the written description requirement. It would neither enforce the quid pro quo between the patentee and the public by forcing the disclosure of new information, nor would it be necessary to demonstrate to a person of ordinary skill in the art that the patentee was in possession of the claimed invention. As we stated in Capon, "[t]he 'written description' requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution." Id. at 1358. Indeed, the forced recitation of known sequences in patent disclosures would only add unnecessary bulk to the specification. Accordingly we hold that where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here "essential genes"), satisfaction of the written

> description requirement does not require either recitation or incorporation by reference [footnote omitted] (wherein permitted) of such genes and sequences.

The holding in *Falkner,* like the holding in *Capon* (and the case law regarding written description generally) previously discussed in the record, establishes once again that the written description rejection in the pending case is unsustainable because it is based on the assertions that only that which is exemplified or reduced to practice is adequately described and that re-description of sequences of known molecules (*e.g.,* histone modifying enzymes) is required to satisfy the written description requirement.

Thus, Applicants again submit, for the reasons of record and reaffirmed in *Falkner,* that clear description is present in the original claims and specification. Because the pending claims define an invention that is novel, non-obvious, fully enabled and described by the specification, Applicant requests that the rejection of the claims be withdrawn, and that the application proceed to allowance.

Respectfully submitted,

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By: _____

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